WE CLAIM:

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- A coated stent (10), comprising:
 a stent latticework (20); and
 an alginate coating (30) disposed on the stent latticework.
- 2. The coated stent of claim 1, wherein the stent latticework includes one of a metallic body and a polymeric body.
- 10 3. The coated stent of claim 2, wherein the stent latticework includes a metallic body, and wherein the metallic body includes at least one metal or metal alloy selected from the group consisting of stainless steel, nitinol, platinum, and titanium.
- 15 4. The coated stent of claim 2, wherein the stent latticework includes a polymeric body, and wherein the polymeric body includes poly-L-lactide.
 - 5. The coated stent of claim 1, wherein the stent latticework is balloon-expandable or self-expandable.
 - 6. The coated stent of claim 1, wherein the alginate coating includes an alginate matrix (32) having a predetermined ratio of mannuronate alginate subunits (62) and guluronate alginate subunits (64).
 - The coated stent of claim 1 further comprising:
 - a therapeutic component (34) dispersed within the alginate coating, wherein the therapeutic component acts as source of a therapeutic agent (40), and wherein the alginate coating controls elution of the therapeutic agent from the alginate coating.

8. The coated stent of claim 7, wherein the therapeutic component is selected from the group consisting of an anti-coagulant, an anti-platelet drug, an anti-thrombotic drug, an anti-proliferant, an inhibitory agent, an anti-stenotic substance, heparin, a heparin peptide, an anti-cancer drug, an anti-inflammatant, nitroglycerin, L-arginine, an amino acid, a nutraceutical, an enzyme, a nitric oxide synthase, a diazeniumdiolate, matrix metalloproteinase, a nitric oxide donor, rapamycin, a rapamycin analog, paclitaxel, a paclitaxel analog, a coumadin therapy, a lipase, and a combination thereof.

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9. The coated stent of claim 1 further comprising:

a cellular component (36) dispersed within the alginate coating, wherein the cellular component controllably releases a therapeutic agent (40) when the coated stent is deployed within a vessel (50) of a mammalian body (52).

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10. The coated stent of claim 9, wherein the cellular component is selected from the group consisting of endothelial cells, manipulated cells of designer deoxyribonucleic acid, host-derived cells from a host source, donor-derived cells from a donor source, pharmacologically viable cells, freeze-dried cells, and a combination thereof.

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11. The coated stent of claim 9, wherein the released therapeutic agent includes nitric oxide.

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12. The coated stent of claim 9, wherein the released therapeutic agent comprises vascular endothelial growth factor, a biological anti-inflammatory agent, vitamin C, acetylsalicylic acid, a lipid-lowering compound, a high-density lipoprotein cholesterol, a streptokinase, a kinase, a thrombolytic agent, an anti-thrombotic agent, a blood-thinning agent, a coumadin material, an anti-cancer agent, a therapeutic component, a cellular component, and a combination thereof.

13. A method of treating a vessel (50) in a mammalian body (52), the method comprising:

providing a stent latticework (20);

coating the stent latticework with an alginate solution (60) to form a coated stent (10) having an alginate coating (30) disposed on the stent latticework;

positioning the coated stent within the vessel;

deploying the coated stent; and

eluting a therapeutic agent (40) from the alginate coating.

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- 14. The method of claim 13, wherein the vessel of the mammalian body is selected from the group consisting of a coronary vessel, a cardiovascular vessel, a carotid artery, a hepatic vein, a hepatic artery, an artery, a vein, a peripheral vessel, an esophagus, a bile duct, a trachea, an intestine, a urethra, and a colon.
- 15. The method of claim 13, wherein coating the stent latticework comprises one of spraying, dipping, and rolling the stent latticework with the alginate solution, the alginate solution including a plurality of alginate subunits (62, 64), an alginate solvent (66), and one of a therapeutic component (34) or a cellular component (36).
- 16. The method of claim 13, wherein the alginate coating controls the elution of the therapeutic agent when the coated stent is deployed.

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17. The method of claim 13, wherein the alginate coating includes one of a therapeutic component (34) or a cellular component (36).

- 18. The method of claim 13, wherein the eluted therapeutic agent is selected from the group consisting of vascular endothelial growth factor, a biological anti-inflammatory agent, vitamin C, acetylsalicylic acid, a lipid lowering compound, a high-density lipoprotein cholesterol, a streptokinase, a kinase, a thrombolytic agent, an anti-thrombotic agent, a blood-thinning agent, a coumadin material, an anti-cancer agent, a therapeutic component, a cellular component, and a combination thereof.
- 19. The method of claim 13, wherein the eluted therapeutic agent comprises nitric oxide to regulate the proliferation of smooth muscle cells in the vessel near the deployed stent.

20. The method of claim 13 further comprising:

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determining a ratio of mannuronate alginate subunits (62) and guluronate alginate subunits (64) to provide a predetermined elution characteristic of the alginate coating;

mixing mannuronate alginate subunits, guluronate alginate subunits, an alginate solvent (66), and one of a therapeutic component (34) or a cellular component (36) to form an alginate solution (60) with the determined ratio of mannuronate alginate subunits and guluronate alginate subunits;

adding an alginate linking agent (68) to the alginate solution; and coating the stent latticework with the alginate solution.

21. The method of claim 20, wherein the added alginate linking agent comprises one of divalent calcium, divalent barium, divalent strontium, or divalent magnesium.

22. The method of claim 13 further comprising:

selecting at least one of a therapeutic component (34) and a cellular component (36); and

mixing the selected at least one component into the alginate solution prior to coating the stent latticework.

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23. The method of claim 13 further comprising:

harvesting a viable cellular component (36) from the mammalian body; and

mixing the harvested viable cellular component into the alginate solution prior to coating the stent latticework.

- 24. The method of claim 23, wherein the harvested viable cellular component comprises endogenous endothelial cells.
- 25. The method of claim 13 further comprising: reconstituting a cellular component (36) in the alginate solution when the coated stent is deployed.
- 26. An alginate coating (30) for an implantable medical device (12), the alginate coating comprising:

an alginate matrix (32); and

at least one of a therapeutic component (34) and a cellular component (36) dispersed within the alginate matrix.

- 27. The alginate coating of claim 26, wherein the implantable medical device is selected from the group consisting of a stent, a valve, a pacemaker lead, a pacemaker, a pacing device, a venous filter, an abdominal aortic abdominal aneurysm device, and a vascular graft.
- 28. An alginate implant (130) for treating a vessel (150) in a mammalian body (152), the alginate implant comprising:

an alginate matrix (132) in contact with an endoluminal wall (154) of the vessel; and

a central lumen (142) axially extending through the alginate matrix.

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The alginate implant of claim 28 wherein the alginate matrix is 29. formed within the vessel from an alginate solution (160) injected into a portion (156) of the vessel.

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The alginate implant of claim 28, wherein the vessel of the 30. mammalian body is selected from the group consisting of a coronary vessel, a cardiovascular vessel, a carotid artery, a hepatic vein, a hepatic artery, an artery, a vein, a peripheral vessel, an esophagus, a bile duct, a trachea, an intestine, a urethra, and a colon.

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The alginate implant of claim 28, wherein the alginate implant 31. has at least one aperture (144) formed in the alginate matrix, the apertures positioned between the central lumen of the alginate implant and the endoluminal wall of the vessel.

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The alginate implant of claim 28, wherein the alginate matrix 32. comprises a predetermined ratio of mannuronate alginate subunits (162) and guluronate alginate subunits (164).

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a therapeutic component (134) dispersed within the alginate matrix,

The alginate implant of claim 28 further comprising:

wherein the alginate matrix controls the elution of a therapeutic agent (140) from the alginate implant.

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The alginate implant of claim 33, wherein the therapeutic 34. component is selected from the group consisting of an anti-coagulant, an antiplatelet drug, an anti-thrombotic drug, an anti-proliferant, an inhibitory agent, an anti-stenotic substance, heparin, a heparin peptide, an anti-cancer drug, an anti-inflammatant, nitroglycerin, L-arginine, an amino acid, a nutraceutical, an enzyme, a nitric oxide synthase, a diazeniumdiolate, a nitric oxide donor, rapamycin, a rapamycin analog, paclitaxel, a paclitaxel analog, a coumadin therapy, a lipase, and a combination thereof.

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35. The alginate implant of claim 28 further comprising:

a cellular component (136) dispersed within the alginate matrix, wherein the alginate matrix controls the elution of a therapeutic agent (140) from the alginate implant.

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- 36. The alginate implant of claim 35, wherein the cellular component is selected from the group consisting of endothelial cells, manipulated cells of designer deoxyribonucleic acid, host-derived cells from a host source, donor-derived cells from a donor source, pharmacologically viable cells, freeze-dried cells, and a combination thereof.
- 37. The alginate implant of claim 35, wherein the eluted therapeutic agent comprises nitric oxide.

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38. The alginate implant of claim 35, wherein the eluted therapeutic agent is selected from the group consisting of vascular endothelial growth factor, a biological anti-inflammatory agent, vitamin C, acetylsalicylic acid, a lipid lowering compound, a high-density lipoprotein cholesterol, a streptokinase, a kinase, a thrombolytic agent, an anti-thrombotic agent, a blood-thinning agent, a coumadin material, an anti-cancer agent, a therapeutic component, a cellular component, and a combination thereof.

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39. The alginate implant of claim 28, wherein the implant is configured as at least one of a stent and a cap for vulnerable plaque.

40. A method of treating a vessel (150) in a mammalian body (152), the method comprising:

forming an alginate implant (130) within the vessel, the alginate implant in contact with an endoluminal wall (154) of the vessel and having a central lumen (142) axially extending through the alginate implant; and

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eluting a therapeutic agent (140) from one of a therapeutic component (134) or a cellular component (136) dispersed within the alginate implant.

- 41. The method of claim 40 wherein the alginate implant controls the elution of the therapeutic agent.
- 42. The method of claim 40, wherein the eluted therapeutic agent is selected from the group consisting of vascular endothelial growth factor, a biological anti-inflammatory agent, vitamin C, acetylsalicylic acid, a lipid lowering compound, a high-density lipoprotein cholesterol, a streptokinase, a kinase, a thrombolytic agent, an anti-thrombotic agent, a blood-thinning agent, a coumadin material, an anti-cancer agent, a therapeutic component, a cellular component, and a combination thereof.
- 43. The method of claim 40, wherein the eluted therapeutic agent comprises nitric oxide to regulate the proliferation of smooth muscle cells in the vessel near the formed alginate implant.
 - 44. The method of claim 40 further comprising:

mixing an alginate solution (160) including an alginate premix and an alginate solvent;

adding an alginate linking agent (168) into the alginate solution; and injecting the alginate solution into a portion (156) of the vessel with an implant formation catheter (110).

- 45. The method of claim 44, wherein the alginate linking agent is added to the alginate solution prior to injecting the alginate solution into the portion of the vessel.
- 46. The method of claim 44, wherein the alginate linking agent is added to the alginate solution after injecting the alginate solution into the portion of the vessel.
- 47. The method of claim 44, wherein the alginate linking agent is deposited on an endoluminal wall (154) of the vessel prior to injecting the alginate solution into the portion of the vessel.

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48. The method of claim 44, wherein the added alginate linking agent comprises one of divalent calcium, divalent barium, divalent strontium, or divalent magnesium.

49. The method of claim 44 further comprising:

determining a ratio of mannuronate alginate subunits (162) and guluronate alginate subunits (164) to provide a predetermined elution characteristic of the alginate implant; and

combining mannuronate alginate subunits, guluronate alginate subunits, the alginate solvent, and the therapeutic component or the cellular component to form the alginate solution with the determined ratio of mannuronate alginate subunits and guluronate alginate subunits.

50. The method of claim 44 further comprising:

harvesting a viable cellular component (136) from a host or a donor; and

mixing the harvested viable cellular component into the alginate solution prior to injecting the alginate solution.

51. The method of claim 50, wherein the harvested viable cellular component comprises endogenous endothelial cells.

52. The method of claim 50 further comprising:

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reconstituting the cellular component in the alginate implant, wherein the eluted therapeutic agent is released from the reconstituted cellular component.

53. A system for forming an alginate implant (130) in a mammalian body (152), the system comprising:

an implant formation catheter (110) having a catheter body (112);

a formation balloon (120) attached to the catheter body near a distal end (114) of the catheter body; and

an alginate-delivery lumen (118) within the catheter body, wherein an alginate implant (130) is formed from an alginate solution (160) injected through the alginate-delivery lumen into a cavity (122) between the formation balloon and an endoluminal wall (154) of the vessel when the formation balloon is inflated.

54. The system of claim 53, wherein the formation balloon has surface features (146) to form at least one aperture (144) in the alginate implant when the alginate solution is injected.

55. A method of forming an alginate implant (130) in a vessel (150) of a mammalian body (152), the method comprising:

positioning an implant formation catheter (110) in the vessel, the implant formation catheter having a catheter body (112);

inflating a formation balloon (120) attached to the catheter body near a distal end (114) of the catheter body;

injecting an alginate solution (160) through an alginate-delivery lumen (118) into a cavity (122) formed between the inflated formation balloon and an endoluminal wall (154) of the vessel; and

hardening the alginate solution to form the alginate implant.

56. The method of claim 55 further comprising: deflating the formation balloon; and withdrawing the implant formation catheter from the vessel.

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57. A system for forming an alginate implant (130) in a mammalian body (152), the system comprising:

an implant formation catheter (110) having a catheter body (112);

a distal occlusion balloon (124) attached to the catheter body near a distal end (114) of the catheter body;

a proximal occlusion balloon (126) attached to the catheter body proximal to the distal occlusion balloon;

a medial formation balloon (128) attached to the catheter body between the distal occlusion balloon and the proximal occlusion balloon; and

an alginate-delivery lumen (118) within the catheter body, wherein an alginate implant (130) is formed from an alginate solution (160) injected through the alginate-delivery lumen into a cavity (122) between the medial formation balloon and an endoluminal wall (154) of the vessel when the distal occlusion balloon and the proximal occlusion balloon are inflated.

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58. The system of claim 57, wherein the medial formation balloon has surface features (146) to form at least one aperture (144) in the alginate implant when the alginate solution is injected.

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59. A method of forming an alginate implant (130) in a vessel (150) of a mammalian body (152), the method comprising:

positioning an implant formation catheter (110) in the vessel, the implant formation catheter having a catheter body (112);

inflating a distal occlusion balloon (124) attached to the catheter body near a distal end (114) of the catheter body;

inflating a proximal occlusion balloon (126) attached to the catheter body proximal to the distal balloon;

inflating a medial formation balloon (128) attached to the catheter body between the distal occlusion balloon and the proximal occlusion balloon;

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injecting an alginate solution (160) through an alginate-delivery lumen (118) into a cavity (122) formed between the inflated distal occlusion balloon, the inflated proximal occlusion balloon, the inflated medial formation balloon, and an endoluminal wall (154) of the vessel; and

hardening the alginate solution to form the alginate implant.

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60. The method of claim 59 further comprising:

deflating the distal occlusion balloon, the proximal occlusion balloon, and the medial formation balloon; and

withdrawing the implant formation catheter from the vessel.

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61. A system for forming an alginate implant (130) in a mammalian body (152), the system comprising:

an implant formation catheter (110) having a catheter body (112);

an angioplasty balloon (170) attached to the catheter body near a distal end (114) of the catheter body, the angioplasty balloon having an alginate linking agent (168) disposed on a surface (172) of the angioplasty balloon;

a formation balloon (120) attached to the catheter body proximal to the angioplasty balloon; and

an alginate-delivery lumen (118) within the catheter body, wherein an alginate implant (130) is formed from an alginate solution (160) injected through the alginate-delivery lumen into a cavity (122) between the formation balloon and an endoluminal wall (154) of the vessel when the formation balloon is inflated.

62. The system of claim 61, wherein the formation balloon has surface features (146) to form at least one aperture (144) in the alginate implant when the alginate solution is injected.

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63. A method of forming an alginate implant (130) in a vessel (150) of a mammalian body (152), the method comprising:

positioning an implant formation catheter (110) at a first location (174) in the vessel, the implant formation catheter having a catheter body (112);

inflating an angioplasty balloon (170) attached to the catheter body near a distal end (114) of the catheter body, the angioplasty balloon having an alginate linking agent (168) disposed on a surface (178) of the angioplasty balloon;

depositing the alginate linking agent on an endoluminal wall (154) of the vessel;

deflating the angioplasty balloon;

repositioning the implant formation catheter at a second location (176) in the vessel, the second location in the vessel distal to the first location in the vessel;

re-inflating the angioplasty balloon;

inflating a formation balloon (120) attached to the catheter body proximal to the angioplasty balloon;

injecting an alginate solution (160) through an alginate-delivery lumen (118) into a cavity (122) formed between the formation balloon and an endoluminal wall (154) of the vessel; and

hardening the alginate solution to form the alginate implant, wherein the alginate solution is hardened by the alginate linking agent deposited on the endoluminal wall of the vessel.

- 64. The method of claim 63, wherein the re-inflated angioplasty balloon serves as a distal protection device.
 - 65. The method of claim 63 further comprising: deflating the angioplasty balloon and the formation balloon; and withdrawing the implant formation catheter from the vessel.

66. The method of claim 65, wherein the angioplasty balloon captures embolic particles when the angioplasty balloon and the formation balloon are deflated.

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67. A system for forming an alginate implant (130) in a vessel (150) of a mammalian body (152), the system comprising:

an implant formation catheter (110) having a catheter body (112) and an alginate-delivery lumen (118) within the catheter body; and

at least one formation balloon (120) attached proximal to a distal end (114) of the catheter body, wherein the alginate implant is formed in the vessel when the implant formation catheter is inserted into the vessel and an alginate solution (160) is injected through the alginate-delivery lumen into a cavity (122) formed between the formation balloon and an endoluminal wall

(154) of the vessel.

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68. A method of forming an alginate implant (130) in a vessel (150) of a mammalian body (152), the method comprising:

inserting an implant formation catheter (110) into the vessel, the implant formation catheter having at least one formation balloon (120);

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injecting an alginate solution (160) into a cavity (122) formed between the formation balloon and an endoluminal wall (154) of the vessel when the formation balloon is inflated;

hardening the alginate solution to form the alginate implant; and

withdrawing the implant formation catheter from the vessel, wherein the formed alginate implant is in contact with the endoluminal wall of the vessel and includes a central lumen (142) axially extending through the alginate implant.

69. An alginate bioreactor (310) for treating a mammalian body (350), the alginate bioreactor comprising:

an alginate matrix (320); and

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one of a therapeutic component (330) or a cellular component (332) dispersed within the alginate matrix, wherein a therapeutic agent (340) is eluted from the alginate matrix after the alginate bioreactor is formed within the body.

- 70. The alginate bioreactor of claim 69, wherein the alginate matrix of the alginate bioreactor is formed from an alginate solution (360) injected into a portion of the body.
- 71. The alginate bioreactor of claim 69, wherein the alginate bioreactor is formed in a portion of the mammalian body, the portion of the mammalian body selected from the group consisting of a heart, a liver, a pancreas, a kidney, an eyeball, a pericardial space, a cerebral spinal space, a periorganic space, an organ, a vessel, and a tissue.
- 72. The alginate bioreactor of claim 69, wherein the alginate matrix comprises a predetermined ratio of mannuronate alginate subunits (362) and guluronate alginate subunits (364).
 - 73. The alginate bioreactor of claim 69, wherein the alginate matrix controls the elution of the therapeutic agent from the alginate bioreactor.

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74. The alginate bioreactor of claim 69, wherein the therapeutic component is selected from the group consisting of an anti-coagulant, an anti-platelet drug, an anti-thrombotic drug, an anti-proliferant, an inhibitory agent, an anti-stenotic substance, heparin, a heparin peptide, an anti-cancer drug, an anti-inflammatant, nitroglycerin, L-arginine, an amino acid, a nutraceutical, an enzyme, a nitric oxide synthase, a diazeniumdiolate, a nitric oxide donor, rapamycin, a rapamycin analog, paclitaxel, a paclitaxel analog, a coumadin therapy, a lipase, a protein, insulin, bone morphogenetic protein, and a combination thereof.

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75. The alginate bioreactor of claim 69, wherein the cellular component is selected from the group consisting of endothelial cells, manipulated cells of designer deoxyribonucleic acid, host-derived cells from a host source, donor-derived cells from a donor source, pharmacologically viable cells, freeze-dried cells, and a combination thereof.

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76. The alginate bioreactor of claim 69, wherein the eluted therapeutic agent comprises nitric oxide.

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77. The alginate bioreactor of claim 69, wherein the eluted therapeutic agent is selected from the group consisting of vascular endothelial growth factor, a biological anti-inflammatory agent, vitamin C, acetylsalicylic acid, a lipid lowering compound, a high-density lipoprotein cholesterol, a streptokinase, a kinase, a thrombolytic agent, an anti-thrombotic agent, a blood-thinning agent, a coumadin material, an anti-cancer agent, an angiogenic agent, an anti-angiogenic agent, an anti-rejection agent, a hormone, a therapeutic component, a cellular component, and a combination thereof.

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78. A method of treating a medical condition in a mammalian body (350), the method comprising:

forming an alginate bioreactor (310) within a portion of the mammalian body, the alginate bioreactor including an alginate matrix (320); and

eluting a therapeutic agent (340) from one of a therapeutic component (330) or a cellular component (332) dispersed within the alginate bioreactor.

- 79. The method of claim 78, wherein forming the alginate bioreactor comprises injecting an alginate solution (360) and an alginate linking agent (368) into the portion of the mammalian body, and hardening the alginate solution to form the alginate bioreactor.
- 80. The method of claim 78, wherein the alginate bioreactor controls the elution of the therapeutic agent.
- 81. The method of claim 78, wherein the eluted therapeutic agent comprises nitric oxide.
- selected from the group consisting of vascular endothelial growth factor, a biological anti-inflammatory agent, vitamin C, acetylsalicylic acid, a lipid lowering compound, a high-density lipoprotein cholesterol, a streptokinase, a kinase, a thrombolytic agent, an anti-thrombotic agent, a blood-thinning agent, a coumadin material, an anti-cancer agent, an angiogenic agent, an anti-angiogenic agent, an anti-cellular component, and a combination thereof.

The method of claim 78 further comprising: 83.

mixing an alginate solution (360) including an alginate premix and an alginate solvent (366);

providing an alginate linking agent (368);

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injecting the alginate solution and the alginate linking agent into a portion of the mammalian body with an alginate injection system (370); and hardening the alginate solution to form the alginate bioreactor.

- The method of claim 83, wherein the alginate linking agent is 84. added to the alginate solution prior to injecting the alginate solution into the portion of the mammalian body.
 - The method of claim 83, wherein the alginate linking agent is 85. added to the alginate solution after injecting the alginate solution into the portion of the mammalian body.
 - The method of claim 83, wherein the alginate linking agent is 86. deposited in the portion of the mammalian body prior to injecting the alginate solution.

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The method of claim 83, wherein the added alginate linking 87. agent comprises one of divalent calcium, divalent barium, divalent strontium, divalent magnesium, or a divalent cation.

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- The method of claim 83, wherein the alginate solution is injected 88. into the portion of the mammalian body with a syringe having at least one lumen.
- The method of claim 83, wherein the alginate solution is injected 89. into the portion of the mammalian body with a bioreactor formation catheter. 30

90. The method of claim 83, wherein the alginate solution is injected into the portion of the mammalian body with a high-pressure jet.

91. The method of claim 83 further comprising:

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determining a ratio of mannuronate alginate subunits (362) and guluronate alginate subunits (364) to provide a predetermined elution characteristic of the alginate bioreactor; and

combining mannuronate alginate subunits, guluronate alginate subunits, the alginate solvent, and the therapeutic component or the cellular component to form the alginate solution with the determined ratio of mannuronate alginate subunits and guluronate alginate subunits.

92. The method of claim 83 further comprising:

harvesting a viable cellular component (332) from one of a host or a donor; and

mixing the harvested viable cellular component into the alginate solution prior to injecting the alginate solution.

93. The method of claim 92, wherein the harvested viable cellular component comprises endogenous endothelial cells.

94. The method of claim 83 further comprising:

reconstituting the cellular component in the alginate bioreactor, wherein the eluted therapeutic agent is released from the reconstituted cellular component.

95. The method of claim 83 further comprising:

genetically manipulating the cellular component prior to forming the alginate bioreactor.

96. A system (370) for forming an alginate bioreactor (310) in a mammalian body (352), the system comprising:

a first chamber (372);

a second chamber (374); and

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an alginate solution injector (376) fluidly coupled to the first chamber and the second chamber, wherein an alginate solution (360) from the first chamber is injected into a portion of the mammalian body with an alginate linking agent (368) from the second chamber to form the alginate bioreactor.

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97. The system of claim 96, wherein the alginate solution injector is selected from the group consisting of a single-lumen syringe, a double-lumen syringe, a bioreactor formation catheter, a high-pressure injection nozzle, and a pair of high-pressure injection nozzles.